# General

## Guideline Title

The use of anti-D immunoglobulin for rhesus D prophylaxis.

## Bibliographic Source(s)

Royal College of Obstetricians and Gynaecologists (RCOG). The use of anti-D immunoglobulin for rhesus D prophylaxis. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2011 Mar. 14 p. (Green-top guideline; no. 22). [37 references]

## Guideline Status

This is the current release of the guideline.

# Recommendations

## Major Recommendations

*In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document.*

Classification of evidence levels (1++ to 4) and grades of recommendations (A-D) are defined at the end of the "Major Recommendations" field.

Test for the Size of Fetomaternal Haemorrhage (FMH)

How Should the Size of FMH Be Quantified?

D - A Kleihauer screening test should be performed within 2 hours of delivery to identify rhesus D (RhD)-negative women with a large FMH who require additional anti-D immunoglobulin (anti-D Ig).

Administration

How Should Anti-D Ig Be Administered?

D - For successful immunoprophylaxis, anti-D Ig should be given as soon as possible after the potentially sensitising event but always within 72 hours. If it is not given before 72 hours, every effort should still be made to administer the anti-D Ig, as a dose given within 10 days may provide some protection.

Prophylaxis Following Miscarriage, Ectopic Pregnancy and Termination of Pregnancy

When Is Anti-D Ig Prophylaxis Required Following Miscarriage, Ectopic Pregnancy and Termination of Pregnancy?

When indicated, anti-D Ig is administered in a dose of 250 IU up to $19^{+6}$ weeks of gestation and in a dose of 500 IU thereafter. A test for the size of FMH should be performed when anti-D Ig is given at or after $20^{+0}$ weeks of gestation.

*Miscarriage*

D - Anti-D Ig should be given to all non-sensitised RhD-negative women who have a spontaneous complete or incomplete miscarriage at or after $12^{+0}$ weeks of gestation.

D - Anti-D Ig is not required for spontaneous miscarriage before $12^{+0}$ weeks of gestation, provided there is no instrumentation of the uterus.

D - Anti-D Ig should be given to non-sensitised RhD-negative women undergoing surgical evacuation of the uterus, regardless of gestation.

D - Anti-D Ig should be considered for non-sensitised RhD-negative women undergoing medical evacuation of the uterus, regardless of gestation.

*Threatened Miscarriage*

D - Anti-D Ig should be given to all non-sensitised RhD-negative women with a threatened miscarriage after $12^{+0}$ weeks of gestation. In women in whom bleeding continues intermittently after $12^{+0}$ weeks of gestation, anti-D Ig should be given at 6-weekly intervals.

D - Anti-D Ig should be considered in non-sensitised RhD-negative women if there is heavy or repeated bleeding or associated abdominal pain as gestation approaches $12^{+0}$ weeks.

*Ectopic Pregnancy*

D - Anti-D Ig should be given to all non-sensitised RhD-negative women who have an ectopic pregnancy, regardless of management.

*Therapeutic Termination of Pregnancy*

D - Anti-D Ig should be given to all non-sensitised RhD-negative women having a therapeutic termination of pregnancy, whether by surgical or medical methods, regardless of gestational age.

Prophylaxis Following Sensitising Events Before Delivery

Which Antenatal Sensitising Events Require Anti-D Ig Prophylaxis?

D - A minimum dose of 250 IU is recommended for prophylaxis following sensitising events up to $19^{+6}$ weeks of gestation. For all events at or after $20^{+0}$ weeks of gestation, a minimum dose of 500 IU anti-D Ig should be given and a test to identify FMH greater than 4 ml red cells performed; additional anti-D Ig should be given as required. [Evidence level 4]

D - In the event of recurrent vaginal bleeding after $20^{+0}$ weeks of gestation, anti-D Ig should be given at a minimum of 6-weekly intervals. [Evidence level 4]

Anti-D Ig should be given to all non-sensitised RhD-negative women after the following potentially sensitising events during pregnancy; this should be in addition to any already received:

- Invasive prenatal diagnosis (amniocentesis, chorion villus sampling, cordocentesis, intrauterine transfusion)
- Other intrauterine procedures (e.g., insertion of shunts, embryo reduction, laser)
- Antepartum haemorrhage
- External cephalic version of the fetus (including attempted)
- Any abdominal trauma (direct/indirect, sharp/blunt, open/closed)
- Fetal death

If there is concern about the frequency of recurrent bleeding, estimation of FMH using a Kleihauer test can be performed at 2-weekly intervals; if positive, an additional dose of anti-D Ig can be administered (500 IU or greater, depending on the size of the FMH). This dose is given irrespective of the presence or absence of passive anti-D.

Routine Antenatal Prophylaxis

How Should a Routine Antenatal Anti-D Prophylaxis (RAADP) Programme Be Put into Clinical Practice?

B - RAADP should be offered to all non-sensitised RhD-negative women. [Evidence level 2+]

C - The routine 28-week antibody screening sample must be taken before administration of the first dose of anti-D. This meets the British Committee for Standards in Haematology requirement for a second antibody screen during pregnancy. [Evidence level 2+]

What Are the Maternal and Fetal Effects of RAADP?

B - There is no evidence to suggest that RAADP is associated with adverse events that are of consequence for the mother or baby, other than the possibility of blood-borne infection, and procedures are in place to minimise these risks.

How Should Women Who Decline RAADP Be Managed?

C - In the event that RAADP is declined antibody screening should be performed at booking and at 28 weeks of gestation to identify cases where sensitisation has occurred. Sensitisation occurring in the third trimester is unlikely to cause significant fetal problems in that pregnancy. [Evidence level 2+]

Some women will decline RAADP, and certain subgroups can be identified:

- Women who object on religious grounds
- Women who will be sterilised after the birth
- Women who are certain they will have no more children
- Women who are in a stable relationship with the genetic father of their children and the father is known or found to be RhD-negative

Although it is desirable to avoid unnecessary RAADP, there are potential problems with the latter two groups: women may change their minds about a further pregnancy, and there are known complexities associated with paternal testing with potential for misidentification of the father.

Women should be given adequate information with which to make an informed choice about accepting or declining anti-D Ig. If a woman declines anti-D Ig, this decision should be acknowledged and the reasons for the decision documented in the case notes.

Postnatal Prophylaxis

Who Should Receive Postnatal Anti-D Ig Prophylaxis?

A/B - At least 500 IU of anti-D Ig must be given to every non-sensitised RhD-negative woman within 72 hours following the delivery of an RhD-positive infant.

C/D - A test to detect FMH greater than 4 ml must also be undertaken so that additional anti-D Ig can be given as appropriate.

D - If the pregnancy is non-viable and no sample can be obtained from the baby, anti-D Ig should be administered to a non-sensitised RhD-negative woman. [Evidence level 4]

Some women who have received anti-D Ig during pregnancy may have detectable anti-D in their blood at delivery. Because it may be difficult or impossible to distinguish between such passive anti-D Ig and weak anti-D resulting from early immunisation, anti-D Ig should be given to any eligible woman with weak anti-D antibody at delivery unless it has been clearly confirmed that she is already sensitised.

Transfusion of RhD-Positive Blood Components

How Should Inadvertent Transfusion of RhD-positive Platelets Be Managed?

D - In the event that RhD-positive platelets are transfused, prophylaxis against Rh alloimmunisation should be given.

Each unit of platelets prepared according to the UK guidelines from one whole blood donation contains fewer than $1 \times 10^9$ (< 0.1 ml red cells). 250 IU (50 micrograms) anti-D Ig should be given following every three adult doses (i.e., derived from up to 18 routine donations) of platelets. Women who have marked thrombocytopenia should be given the anti-D Ig subcutaneously to avoid the possibility of a haematoma following intramuscular injection.

How Should Inadvertent Transfusion of RhD-positive Blood Be Managed?

D - Anti-D Ig should be given to RhD-negative women of reproductive capacity who inadvertently receive a transfusion of RhD-positive blood.

D - The dose should be calculated on the basis that 500 IU of anti-D Ig will suppress immunisation by 4 ml of RhD-positive red blood cells.

D - Exchange transfusion may be necessary for large volumes of transfused blood.

When less than 15 ml of RhD-positive blood has been transfused to an RhD-negative woman capable of childbearing, the appropriate dose of anti-D Ig should be given. When more than 15 ml has been transfused, it is preferable to use the larger anti-D Ig intramuscular preparation (2500 IU or 5000 IU).

When more than two units of RhD-positive blood have been transfused, consideration should be given to undertaking an exchange transfusion to reduce the load of RhD-positive red blood cells in the circulation and the dose of anti-D Ig required to suppress immunisation. In this situation, the woman should be counselled regarding the implications of both non-intervention (for future pregnancies) and of treatment, including any hazards from receiving donated blood, the exchange procedure itself and of larger doses of anti-D Ig including intravenous anti-D Ig.

Immediate exchange transfusion will reduce the load of RhD-positive red cells (a single-blood-volume exchange will achieve a 65%–70% reduction in RhD-positive cells, and a two-volume exchange 85%–90%). Following exchange transfusion, the residual volume of RhD-positive red cells should be estimated using flow cytometry or rosetting. Intravenous anti-D Ig is the preparation of choice, achieving adequate plasma levels immediately and being twice as effective microgram for microgram as intramuscular anti-D Ig at clearing red cells. The dose to be administered should assume that 600 IU of intravenous anti-D Ig will suppress immunisation by 10 ml of fetal red cells. Intravenous anti-D Ig is available for use in the UK on a named patient basis only as WinRho SDF or Rhophylac. Intramuscular anti-D Ig must not be given intravenously. An appropriate combined dose of intravenous and intramuscular anti-D Ig should be determined in discussion with a specialist in transfusion medicine. Follow-up tests for RhD-positive red cells should be undertaken every 48 hours and further anti-D Ig given until all RhD-positive red cells have been cleared from the circulation. Free anti-D in the woman's serum does not necessarily reflect adequate prophylaxis and anti-D Ig treatment should be continued until RhD-positive red cells are no longer detectable.

Passive anti-D Ig given in large doses may be detectable for up to 6 months or more and tests for immune anti-D may not be conclusive for 9–12 months.

Definitions:

Grades of Recommendations

A - At least one meta-analysis, systematic review or randomised controlled trial rated as 1++ and directly applicable to the target population; *or*

A systematic review of randomised controlled trials or a body of evidence consisting principally of studies rated as 1+ directly applicable to the target population and demonstrating overall consistency of results

B - A body of evidence including studies rated as 2++ directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C - A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D - Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

Good Practice Point - Recommended best practice based on the clinical experience of the guideline development group

Classification of Evidence Levels

1++ High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias

1– Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias

2++ High-quality systematic reviews of case–control or cohort studies or high-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal

2+ Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship

is causal

2– Case–control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal

3 Non-analytical studies, e.g., case reports, case series

4 Expert opinion

### Clinical Algorithm(s)

None provided

## Scope

### Disease/Condition(s)

- Pregnancy in rhesus D (RhD)-negative women
- RhD alloimmunisation

### Guideline Category

Diagnosis

Management

Prevention

Screening

### Clinical Specialty

Family Practice

Hematology

Internal Medicine

Obstetrics and Gynecology

Pediatrics

### Intended Users

Advanced Practice Nurses

Hospitals

Nurses

Physician Assistants

Physicians

### Guideline Objective(s)

To provide recommendations for the management of the non-sensitised rhesus D (RhD)-negative woman

## Target Population

Non-sensitised rhesus D (RhD)-negative woman

## Interventions and Practices Considered

1. Kleihauer screening test to quantify the size of fetomaternal haemorrhage (FMH)
2. Anti-D immunoglobulin (anti-D Ig) immunoprophylaxis (dosage and administration)
3. Anti-D Ig prophylaxis following miscarriage, threatened miscarriage, ectopic pregnancy, termination of pregnancy
4. Anti-D Ig prophylaxis following sensitising events before delivery
5. Routine antenatal anti-D prophylaxis (RAADP)
6. Management of women who decline RAADP
7. Postnatal anti-D Ig prophylaxis
8. Management of inadvertent transfusion of rhesus D (Rh-D) positive blood components (anti-D Ig prophylaxis, exchange transfusion)

## Major Outcomes Considered

- Incidence of rhesus alloimmunisation in previously non-sensitised RhD (rhesus D) negative women
- Deaths attributed to RhD alloimmunisation
- Accuracy of diagnostic tests

# Methodology

## Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

This Royal College of Obstetricians and Gynaecologists (RCOG) guideline was developed in accordance with standard methodology for producing RCOG Green-top guidelines. The Cochrane Library (including the Cochrane Database of Systematic Reviews), DARE, EMBASE, TRIP, Medline and PubMed (electronic databases) were searched for relevant randomised controlled trials, systematic reviews and meta-analyses. The search was restricted to articles published between 1999 and February 2010. The databases were searched using the relevant MeSH terms, including all subheadings, and this was combined with a keyword search. Search words included 'Rho (D) immune globulin', 'Rh isoimmunization', 'isoantibodies', 'rhesus disease', 'Rh D haemolytic disease', 'erythroblastosis fetalis', 'Rho (D) antigen', 'RHO (D) antibody', 'anti D', 'dose, dosage', 'pregnancy', 'drug toxicity', and ' anti D, reaction', and the search was limited to humans and the English language. The National Library for Health and the National Guideline Clearinghouse were also searched for relevant guidelines and reviews.

## Number of Source Documents

Not stated

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

Classification of Evidence Levels

1++ High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias

1– Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias

2++ High-quality systematic reviews of case–control or cohort studies or high-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal

2+ Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal

2– Case–control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal

3 Non-analytical studies, e.g., case reports, case series

4 Expert opinion

## Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

## Description of the Methods Used to Analyze the Evidence

Reviewing and Grading of Evidence

Once the evidence has been collated for each clinical question it needs to be appraised and reviewed (refer to section 3 in "Development of RCOG Green-top guidelines: producing a clinical practice guideline" for information on the formulation of the clinical questions; see the "Availability of Companion Documents" field). For each question, the study type with least chance of bias should be used. If available, randomised controlled trials (RCTs) of suitable size and quality should be used in preference to observational data. This may vary depending on the outcome being examined.

The level of evidence and the grade of the recommendations used in this guideline originate from the guidance by the Scottish Intercollegiate Guidelines Network (SIGN) Grading Review Group, which incorporates formal assessment of the methodological quality, quantity, consistency, and applicability of the evidence base. The methods used to appraise individual study types are available from the SIGN Web site (www.sign.ac.uk/methodology/checklists.html ). An objective appraisal of study quality is essential, but paired reviewing by guideline leads may be impractical because of resource constraints.

Once evidence has been collated and appraised, it can be graded. A judgement on the quality of the evidence will be necessary using the grading system (see the "Rating Scheme for the Strength of the Evidence" field). Where evidence is felt to warrant 'down-grading', for whatever reason, the rationale must be stated. Evidence judged to be of poor quality can be excluded. Any study with a high chance of bias (either 1– or 2–) will be excluded from the guideline and recommendations will not be based on this evidence. This prevents recommendations being based on poor-quality RCTs when higher-quality observational evidence is available.

## Methods Used to Formulate the Recommendations

Expert Consensus

Informal Consensus

## Description of Methods Used to Formulate the Recommendations

Guideline Development

The development of guidelines involves more than the collation and reviewing of evidence. Even with high-quality data from systematic reviews of randomised controlled trials, a value judgement is needed when comparing one therapy with another. This will therefore introduce the need for consensus.

Royal College of Obstetricians and Gynaecologists (RCOG) Green-top guidelines are drafted by nominated developers, in contrast to other guideline groups such as the National Institute for Health and Clinical Excellence (NICE) and the Scottish Intercollegiate Guidelines Network (SIGN), who use larger guideline development groups. Equally, in contrast to other guideline groups, the topics chosen for development as Green-top guidelines are concise enough to allow development by a smaller group of individuals.

In agreeing the precise wording of evidence-based guideline recommendations and in developing consensus-based 'good practice points', the Guidelines Committee (GC) will employ an informal consensus approach through group discussion. In line with current methodologies, the entire development process will follow strict guidance and be both transparent and robust. The RCOG acknowledges that formal consensus methods have been described, but these require further evaluation in the context of clinical guideline development. It is envisaged that this will not detract from the rigor of the process but prevent undue delays in development.

## Rating Scheme for the Strength of the Recommendations

Grades of Recommendations

A - At least one meta-analysis, systematic review or randomised controlled trial rated as 1++ and directly applicable to the target population; *or*

A systematic review of randomised controlled trials or a body of evidence consisting principally of studies rated as 1+ directly applicable to the target population and demonstrating overall consistency of results

B - A body of evidence including studies rated as 2++ directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C - A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D - Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

Good Practice Point - Recommended best practice based on the clinical experience of the guideline development group

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

## Method of Guideline Validation

External Peer Review

Internal Peer Review

## Description of Method of Guideline Validation

Following discussion in the Guidelines Committee (GC), each Green-top guideline is formally peer reviewed. At the same time, the draft guideline

is published on the Royal College of Obstetricians and Gynaecologists (RCOG) Web site for further peer discussion before final publication.

All comments will be collated by the RCOG and tabulated for consideration by the guideline leads. Each comment will require discussion. Where comments are rejected then justification will need to be made. Following this review, the document will be updated and the GC will then review the revised draft and the table of comments.

Once the GC signs-off on the guideline, it is submitted to the Standards Board for approval before final publication.

# Evidence Supporting the Recommendations

## Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for most recommendations (see the "Major Recommendations" field).

# Benefits/Harms of Implementing the Guideline Recommendations

## Potential Benefits

- Post-delivery immunoprophylaxis using anti-D immunoglobulin (anti-D Ig) in a rhesus D (RhD)-negative woman with an RhD-positive fetus leads to reduced infant deaths attributed to RhD alloimmunisation.
- There is evidence that routine antenatal anti-D prophylaxis (RAADP) given in a first pregnancy continues to confer benefit in subsequent pregnancies, although the mechanism for this remains unexplained.

## Potential Harms

There is no evidence to suggest that routine antenatal anti-D prophylaxis (RAADP) is associated with adverse events that are of consequence for the mother or baby, other than the possibility of blood-borne infection, and procedures are in place to minimise these risks.

# Qualifying Statements

## Qualifying Statements

The Royal College of Obstetricians and Gynaecologists (RCOG) produces guidelines as an educational aid to good clinical practice. They present recognised methods and techniques of clinical practice, based on published evidence, for consideration by obstetricians and gynaecologists and other relevant health professionals. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor or other attendant in the light of clinical data presented by the patient and the diagnostic and treatment options available. This means that RCOG guidelines are unlike protocols or guidelines issued by employers, as they are not intended to be prescriptive directions defining a single course of management. Departure from the local prescriptive protocols or guidelines should be fully documented in the patient's case notes at the time the relevant decision is taken.

# Implementation of the Guideline

## Description of Implementation Strategy

An implementation strategy was not provided.

## Implementation Tools

Audit Criteria/Indicators

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Staying Healthy

## IOM Domain

Effectiveness

Patient-centeredness

# Identifying Information and Availability

## Bibliographic Source(s)

Royal College of Obstetricians and Gynaecologists (RCOG). The use of anti-D immunoglobulin for rhesus D prophylaxis. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2011 Mar. 14 p. (Green-top guideline; no. 22). [37 references]

## Adaptation

The recommendations in this edition of the guideline are taken from the following sources:

- National Institute for Health and Clinical Excellence. Routine antenatal anti-D prophylaxis for women who are rhesus D negative (TA156). London: NICE; 2008 [http://guidance.nice.org.uk/TA156 ].
- Pilgrim H, Lloyd-Jones M, Rees A. Routine antenatal anti-D prophylaxis for RhD-negative women: a systematic review and economic evaluation. *Health Tech Assess* 2009;13:iii, ix–x1, 1–103.

## Date Released

2011 Mar

## Guideline Developer(s)

Royal College of Obstetricians and Gynaecologists - Medical Specialty Society

## Source(s) of Funding

Royal College of Obstetricians and Gynaecologists

## Guideline Committee

Guidelines Committee

## Composition of Group That Authored the Guideline

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*Committee Lead Peer Reviewers*: Mr Griffiths FRCOG, Luton; Dr SK Surendran FRCOG, London

## Financial Disclosures/Conflicts of Interest

Conflicts of interest: none declared.

## Guideline Status

This is the current release of the guideline.

## Guideline Availability

Electronic copies: Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site .

## Availability of Companion Documents

The following are available:

- Development of RCOG Green-top guidelines: policies and processes. Clinical Governance Advice No 1a. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Nov. 6 p. Electronic copies: Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site .
- Development of RCOG Green-top guidelines: producing a scope. Clinical Governance Advice No 1b. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Nov. 4 p. Electronic copies: Available from the RCOG Web site .
- Development of RCOG Green-top guidelines: producing a clinical practice guideline. Clinical Governance Advice No 1c. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Nov. 13 p. Electronic copies: Available from the RCOG Web site .
- Development of RCOG Green-top guidelines: consensus methods for adaptation of Green-top guidelines. Clinical Governance Advice No 1d. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2010 Feb. 9 p. Electronic copies: Available from the RCOG Web site .

In addition, suggested audit topics can be found in section 13 of the original guideline document .

## Patient Resources

None available

## NGC Status

This NGC summary was completed by ECRI Institute on January 26, 2012.

## Copyright Statement



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